**PSJ14 Janssen Opp Exh 30 – ODM 005447**

# ODJFS P&T Committee Meeting Minutes

June 29, 2011
77 S. High St., 31st floor South A&B

Committee members present: Susan Baker, APN; Suzanne Eastman, RPh; Ioanna Giatis, DO; Robert Hunter, DO (chair); Karen Jacobs, DO; Margaret Scott, RPh; Michael Wascovich, RPh; Mary Jo Welker, MD

ACS staff present: Stephanie Levine, RPh, Clinical Manager, Denise Hefley, PharmD, Clinical Pharmacist

Approximately 90 stakeholders were present, most representing pharmaceutical manufacturers and advocacy associations.

Beginning at 9:00 AM, pharmaceutical manufacturers were given the opportunity to present clinical information on their products and respond to questions from the Committee members.

The meeting was called to order at 12:30 PM.

1. Interested party presentations
   a. Aaron Boster, MD
      Dr. Boster reports relationships as a consultant for Teva Neuroscience, Biogen Idec, and Novartis; lecturer for Teva Neuroscience and Biogen Idec; and clinical trial research with Teva Neuroscience, Biogen Idec, Novartis, Roche, Acorda and Actellion
   b. Robert J. Masone, MD
      Dr. Masone reports relationships as a speaker for Nucynta (Ortho-McNeil), Cymbalta (Lilly), and Naprelan and Rybix (Victory Pharma)
   c. NAMI Ohio, Betsy Johnson
      NAMI Ohio reports that in fiscal year 2010, approximately 5% of their funding was received from corporate members including some pharmaceutical companies
   d. American Lung Association of Ohio, Shelly Kiser
      The American Lung Association of Ohio reports receiving in the past funding from pharmaceutical companies for program and advocacy activities.
   e. Ohio Psychiatric Physicians Association, Janet Shaw
      OPPA reports no conflicts of interest
   f. Ms. Valerie Vernon
      Ms. Vernon reports no conflict of interest

2. Preferred Drug List (PDL) proposal

Dr. Hunter recognized Dr. Hefley to present recommendations from ACS, the Medicaid managed care plans, and ODJFS for the preferred drug list (PDL). A copy of the presentation used by ACS showing clinical changes in each drug class, market share, and recommendations, is attached to this document. The minutes reflect only those drug



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classes that produced discussion. The recommendations presented for all other drug classes were approved unanimously by the committee.

Analgesic Agents: Gout
The length of prior authorization was discussed. A one-year authorization was approved unanimously.

Analgesic Agents: Opioids
Dr. Jacobs noted that there are many opioids available without prior authorization, and she is sensitive to addiction issues in Ohio.
Dr. Hunter said he is in favor of Nucynta based on the potential for less diversion.
The committee voted 7 to 1 in favor of preferred status for Nucynta.

Blood Formation, Coagulation, and Thrombosis Agents: Platelet Aggregation Inhibitors
Ms. Baker noted that Effient may be needed for patients who are determined to be a non-responder to Plavix based on genetic testing.
Mr. Wascovich said that the doctors who presented information in the morning session classified Effient as superior to Plavix.
Dr. Hunter commented that he generally defers to the interventional cardiologist that performed the procedure.
Dr. Welker noted that the cardiologist is not likely to request a prior authorization.
Mr. Wascovich noted the narrow indication of Effient, and wondered whether it would be prescribed when Plavix is indicated.
Dr. Welker thought that more prescriptions for Effient would be written, in part to avoid drug interactions with Plavix and omeprazole. She said that primary care providers should change from omeprazole to ranitidine to avoid the interaction.
Mr. Wascovich suggested adding Effient to preferred status, with a retrospective drug utilization review (DUR) to be done in 6 months. The committee voted 5 to 3 in favor of preferred status for Effient.

Cardiovascular Agents: Lipotropics
Dr. Hunter noted that Welchol has 53% of the market share for bile acid sequestrants, and that in his practice he is unable to convince patients to take powder cholestyramine. In addition, Welchol is useful in diabetes.
Dr. Hunter and Dr. Welker both said that their patients have gastrointestinal side effects from colestipol.
The committee voted 7 to 1 in favor of preferred status for Welchol.
Dr. Giatis noted the prior authorization requirement for statins for no less than two agents used for a one-month trial, and said that Crestor has great data.
Dr. Welker said that Lovaza is needed as an alternative for patients with lipid profiles.
Mr. Wascovich agreed that there are no other similar drugs, and Dr. Jacobs noted that it also has a specific indication.
The committee voted 6 to 2 in favor of preferred status for Lovaza.

Central Nervous System Agents: Anti-Migraine Agents

The committee voted 7 to 1 in favor of keeping Maxalt and Maxalt MLT in preferred status.
If Maxalt is in preferred status, the prior authorization criteria requiring therapeutic trials of two medications not requiring prior approval is appropriate.

Central Nervous System Agents: Antidepressants
Dr. Welker noted the high market share of Cymbalta but also noted the grandfathering policy. Ms. Scott confirmed that patients stable on an antidepressant must be allowed to continue the drug for both fee-for-service and managed care plans, as required by House Bill (HB) 153 (the state budget bill). Dr. Jacobs said that low doses of venlafaxine ER do not have a norepinephrine effect, only Cymbalta and Pristiq are true serotonin-norepinephrine reuptake inhibitors at any dose and at least one is necessary.
The committee voted 7 to 1 in favor of keeping preferred status for Cymbalta.
Dr. Jacobs also noted that the language in HB 153 only exempts psychiatrists from prior authorization when the prescription is in accordance with FDA-approved indications. Many antidepressants are not approved for all indications in all age groups, particularly the child and adolescent population. Ms. Scott said that the department worked with the legislature and managed care plans on the bill language to include FDA-approved indications because of the concern of high prescribing of atypical antipsychotics for young children; however Ms. Scott acknowledged that the language does allow prior authorization for off-label indications as well.

Central Nervous System Agents: Antipsychotics, Second Generation, Oral
Dr. Jacobs noted that the discussion regarding HB 153 also applies to the antipsychotics. Many drugs are approved for acute mania, but not for maintenance therapy. Ms Scott reiterated that patients stable on the drug must be allowed to continue the drug.
Dr. Jacobs also said that she is impressed with Latuda, with few side effects and the convenience of once daily dosing. Dr. Welker said that primary care providers rarely prescribe antipsychotics before a patient has seen a psychiatrist.
The committee voted 7 to 1 to keep Latuda in non-preferred status.

Central Nervous System Agents: Attention Deficit Hyperactivity Disorder Agents
Dr. Jacobs noted that Intuniv and Kapvay are both non-controlled options that should be considered. Ms. Eastman agreed that both drugs should be added to preferred status.
Mr. Wascovich said that the morning speaker for Kapvay said that in Texas, after Kapvay was assed to the PDL the number of prescriptions for atypical antipsychotics for children decreased.
Dr. Hunter said that the market share slide for sympatholytic antihypertensives showed high prescribing of clonidine and guanfacine, and wondered how much was for children.
Dr. Jacobs said that the child psychiatrists at her institution have more experience with Intuniv than with Kapvay.
The committee voted 6 to 2 to add Intuniv and Kapvay to preferred status.
The committee also asked the department to look at the age of patients on clonidine and guanfacine, and to do a retrospective DUR in 6 months.

The committee also voted unanimously to change the length of authorizations to 1 year for all medications in the class.

Central Nervous System Agents: Fibromyalgia
Dr. Giatis said that since the state is trying to decrease prescribing of opioids, at least one agent should be preferred.
The committee voted 7 to 1 to move Cymbalta, Lyrica, and Savella to preferred status.

Central Nervous System Agents: Multiple Sclerosis Agents
Dr. Giatis said that Gilenya is used by the Cleveland Clinic Mellen Center for Multiple Sclerosis Treatment and Research as first line therapy. As one speaker noted, "time is brain." Oral therapy will increase compliance, and enable more patients who do not want to take injections to be treated.
The committee voted 7 to 1 to move Gilenya to preferred status.

Central Nervous System Agents: Sedative-Hypnotics
Dr. Jacobs said that she would like to see a non-controlled option. Ms. Scott said that one of the criteria for approval of non-controlled options is a history of addiction.
The committee noted that there is no time frame for therapeutic trials of preferred medications. Ms. Scott and Ms. Levine were not able to recall the protocol used by the ACS call center and will report back to the committee.

Central Nervous System Agents: Smoking Deterrents
Mr. Wascovich asked why the recommendation is to move Chantix to non-preferred status. Ms. Scott said that all of the managed care plans would like to require prior authorization, so the fee-for-service program is trying to align with the plans.
Dr. Welker said that a lot of her patients will not take Chantix because of the side effects.
Dr. Hunter said that he has had remarkable success with Chantix for his patients. Dr. Huffman, the committee pediatrician who was unable to attend the meeting made it known to the committee, she was against placing Chantix on the preferred list.
The committee voted 7 to 1 to keep Chantix in preferred status.

Endocrine Agents: Diabetes Adjunctive Therapy
Dr. Giatis noted that international recommendations for diabetes are to start patients on dual therapy if hemoglobin A1c is greater than 9.

Gastrointestinal Agents: Ulcerative Colitis Agents
Dr. Welker noted the unique mechanism of action of Lialda.
The committee voted 7 to 1 in favor of placing Lialda in preferred status.

Genitourinary Agents: Benign Prostatic Hyperplasia
Dr. Giatis said that Avodart works better than finasteride, but thought that a one-month trial of finasteride is fine.

Genitourinary Agents: Urinary Antispasmodics

Dr. Hunter noted that his nursing home patients do well on Toviaz. Dr. Giatis agreed but noted that the class requires only a one-month trial of a preferred agent so if cognitive side effects manifest the patient can be changed quickly.

Infectious Disease Agents: Antibiotics – Quinolones
Ms. Eastman asked about the new generic levofloxacin. Ms. Scott said that it was just approved and has not yet been reviewed for pricing. This will be brought back to the committee at the October meeting.

Respiratory Agents: Nasal Preparations
Dr. Huffman, the committee pediatrician, was not able to attend the meeting but communicated with Ms. Scott that Nasonex is indicated for ages 2 and over, while fluticasone is indicated for age 4 and over. She recommended an allowance for patients under age 4 for Nasonex. Ms. Scott said that Nasacort AQ, Nasonex and Veramyst are all indicated for ages 2 and over.
Ms. Eastman asked about the new generic Nasacort AQ. Ms. Scott said that similar to the new generic levofloxacin, it was just approved and has not yet been reviewed.
Ms. Baker said that Veramyst has data showing improvement in ocular symptoms. Dr. Hefley noted that other agents have similar data.
Ms. Scott said that if the committee wants to add a third agent, she would recommend Nasacort AQ because of the recent generic availability and indication for age 2 and over.
The committee voted unanimously to add Nasacort AQ or its generic to preferred status.

Topical Agents: Anti-Parasitics
Ms. Baker noted that Ulesfia is non-toxic, and that often patients come to her after having purchased products over-the-counter (OTC).
Ms. Scott noted that if patients have tried OTC products, the prescriber can submit a prior authorization stating this and the non-preferred agent can be approved.
Dr. Huffman had communicated that lindane is toxic so should be removed from the PDL if possible, or at least include a note that it should not be used in patients under the age of two.

Topical Agents: Pleuromutilin Derivatives
Ms. Scott noted that the smaller tubes of Altabax have been discontinued. ODJFS had originally approved only the 5g and 10g sized, because the manufacturer had said that patients should not need larger tubes. However, very few prescriptions were written for the smaller tube sizes so the manufacturer discontinued those and continued to market only the larger tubes. The larger tubes are much more expensive. The criteria do not include a length of trial or number of other medications to be tried because the smaller tubes were available. The committee asked that this be brought back in October with recommendations about prior therapy.

The meeting was adjourned with a reminder that the next meeting is Wednesday, October 12 at 10 AM.

Notes from ODJFS after the meeting:

The current prior authorization criteria for sedative-hypnotics used by the ACS call center is a history of a claim for a preferred product filled at least 10 days, but not more than 45 days, prior to the prior authorization request.

Committee recommendations regarding length of prior authorizations and addition of Nasacort AQ or its generic will be implemented by the department. The department will also add indicated ages for Second Generation Antihistamines, Nasal Preparations, and Anti-Parasitics and generic names for all drugs to the PDL document as requested by committee members.

The department is reviewing the recommendations for Nucynta, Effient, Welchol, Lovaza, Maxalt, Maxalt MLT, Cymbalta for depression, Intuniv, Kapvay, Cymbalta for fibromyalgia, Lyrica, Savella, Gilenya, Chantix, and Lialda.